

December 21, 2000

EA-00-178

Joel Timberlake, Vice President
Imaging Operations
Mallinckrodt, Inc.
675 McDonnell Boulevard
P. O. Box 5840
St. Louis, MO 63134

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -
\$125,000 (NRC INSPECTION REPORT No. 030-00001/2000-003(DNMS))

Dear Mr. Timberlake:

This refers to the special inspection conducted July 17 through 19, and August 3 through 4, 2000, at the Mallinckrodt, Inc., Maryland Heights, Missouri, facility. The purpose of the July inspection was to follow up on the findings of an inspection performed May 4 through 26, 2000 by an Augmented Inspection Team (AIT) and the August inspection was to follow up on a July 31, 2000, event. The AIT reviewed Mallinckrodt's identification of multiple occupational extremity exposures in excess of the NRC's 0.5 sievert (50 rem) shallow dose equivalent (SDE) limit. The AIT's findings were transmitted to you by letter dated July 14, 2000. The special inspection report was sent to you by letter dated September 5, 2000. On September 28, 2000, a predecisional enforcement conference was conducted in the NRC Region III office with you and members of your staff to discuss the apparent violations, their significance, their root causes, and Mallinckrodt's corrective actions.

Based on the information developed during the inspection and the information that you provided during the conference, the NRC has determined that violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are discussed below and described in detail in the subject inspection report.

The violations in Section A of the Notice involve the failure to: 1) control activities such that the extremity dose to individual workers does not exceed 0.5 sievert (50 rem) shallow dose equivalent (31 examples ranging from 0.54 to at least 5.10 sievert (54 to 510 rem)); 2) use procedures and engineering controls to maintain doses as low as is reasonably achievable (ALARA); and 3) make necessary surveys to ensure that the assigned shallow dose equivalent was for the part of the extremity receiving the highest exposure.

Specifically, on March 31, 2000, a contract employee removed a generator column containing 703 gigabecquerels (19 curies) of molybdenum-99 and 296 gigabecquerels (8 curies) of technetium-99m with his hand while stationed at the rework station of the dry-top-eluting generator manufacturing line. Based on information Mallinckrodt has provided to date, the calculated exposure to the individual's thumb and forefinger is at least 5.10 sievert (510 rem) SDE. Mallinckrodt's investigation into this event identified two processing areas where

additional overexposures had occurred. The first area, in which overexposures occurred between 1996 and 2000¹, involved ten individuals on Mallinckrodt's indium-111 processing line who had handled and received exposures from NRC-licensed material. As a result of handling unshielded vials of millicurie quantities of indium-111 during the process of labeling the vials, these individuals received additional doses to the extremities. The total occupational extremity exposures to these individuals ranged from 0.54 to 3.19 sievert (54 to 319 rem) SDE. The second area involved Sterility Laboratory personnel handling unshielded vials and syringes of millicurie quantities of radioactive materials during sterility testing. These exposures occurred between 1997 and 1999, and involved four individuals. The individuals received exposures in excess of the NRC regulatory limit ranging from 0.68 to 0.96 sievert (68 to 96 rem) SDE. In summary, Mallinckrodt's investigation and NRC's inspection identified 31 overexposures, involving 15 individuals between 1996 and 2000, inclusive, ranging from 0.54 to 5.10 sievert (54 to 510 rem) SDE, with six exposures greater than 2.5 sievert (250 rem) SDE. Contributing to the overexposures were the violations associated with the failure to perform adequate surveys and the failure to use engineering controls to maintain doses ALARA. The failure to perform adequate surveys reflects Mallinckrodt's failure to recognize the substantial difference in dose to the extremity badges and the part of the extremity receiving the highest dose. Individuals hand labeled vials containing an indium-111 product rather than using an automated labeler, which was available but needed modification to label the smaller vials containing indium. Individuals in the Sterility Laboratory directly handled vials and syringes containing radioactive material rather than using shielding to reduce extremity exposures. Therefore, these violations are categorized collectively in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600, May 1, 2000, as a Severity Level I problem.

In accordance with the Enforcement Policy, a base civil penalty in the amount of \$27,500 is considered for a Severity Level I problem. Because your facility has been the subject of an escalated enforcement action within the last two years, the NRC considered whether credit was warranted for *Identification and Corrective Action* in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy. Credit is not warranted for identification since the violations were identified through an event and Mallinckrodt identified multiple precursor events involving similar activities (not resulting in an overexposure), but did not recognize them as radiologically significant. Credit for corrective action is warranted. Specifically, as a result of the identified overexposures, Mallinckrodt agreed to issuance of an Order confirming that Mallinckrodt, among other things, would conduct independent assessments to evaluate operations; provide the NRC a schedule for implementing corrective actions associated with any identified findings; and provide justification to the NRC for any corrective actions not implemented.

While the NRC recognizes that application of the Enforcement Policy would have resulted in a base civil penalty for the Severity Level I problem, the NRC has decided to exercise discretion in accordance with Section VII.A.1 of the Enforcement Policy to increase the penalty. Specifically, the value of the civil penalty for the Severity Level I problem has been increased due to: 1) the number of overexposures (31 overexposures); 2) the severity of the

¹ Four additional overexposures occurred in 1995 and are not included in the Notice or considered in the civil penalty assessment process due to the fact that they occurred over five years ago. Information concerning these exposures is included in our letter dated September 5, 2000.

overexposures (six exposures greater than 2.5 sievert (250 rem) SDE and one exposure of at least 5.10 sievert (510 rem)); 3) the time frame over which the exposures occurred; 4) your poor performance in not identifying the exposures nor the potential for the exposures even though there were multiple precursor events; and, 5) your poor enforcement history.

Therefore, to emphasize the importance of compliance with dose limits, the need for effective evaluations, and in recognition of Mallinckrodt's previous escalated enforcement action, I have been authorized, after consultation with the Commission, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$125,000 for the Severity Level I problem. In addition, issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection effort.

The violations in Section B of the Notice involve the failure to: 1) make necessary surveys to ensure that extremity doses are within regulatory limits; and 2) conduct a radiological evaluation of the dry-top-eluting generator manufacturing line prior to its first use, in accordance with license commitments. The first violation involved an individual who on July 31, 2000, held a generator column containing 703 gigabecquerels (19 curies) of molybdenum-99 by the needle of the column. In this case an inadequate evaluation of the generator survey data caused the individual to believe that the column did not contain radioactive material. While this individual only received an extremity exposure of 0.003 sievert (0.3 rem) SDE, there was substantial potential for the individual to receive an extremity exposure in excess of the NRC regulatory limit (0.5 sievert (50 rem)) if he had grasped the column instead of the needle. Therefore, this violation is categorized in accordance with the Enforcement Policy at Severity Level III.

In accordance with the Enforcement Policy, a base civil penalty in the amount of \$13,750 is considered for a Severity Level III violation. Because your facility has been the subject of an escalated enforcement action within the last two years, the NRC considered whether credit was warranted for *Identification and Corrective Action* in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy. Credit is warranted for identification since your staff identified the inappropriate handling of the generator column. Credit for corrective action is warranted since your staff appropriately evaluated the radiological consequence of the exposure, conducted facility-wide meetings to inform employees of the event, removed the area coordinator and one technician from the dry-top-eluting generator manufacturing line until the event evaluation was completed, and required that the generator manufacturing laboratory supervisor and health physics supervisor be present during generator manufacturing. Therefore, to encourage prompt identification and comprehensive correction of violations, I am authorized not to propose a civil penalty for this violation.

The second violation described in Section B of the Notice addresses the failure to conduct a radiological evaluation on the dry-top-eluting generator manufacturing line in accordance with License Condition No. 20.A. This violation is categorized in accordance with the Enforcement Policy at Severity Level IV.

The NRC has concluded that: the reasons for the violations are already adequately addressed in Inspection Report No. 030-00001/2000-003(DNMS); information regarding initial corrective actions is documented in your letter dated May 26, 2000; and, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance is achieved will be submitted in the schedule of corrective actions required by the June 22, 2000,

Confirmatory Order Modifying License. Therefore, you are not required to respond pursuant to the provisions of 10 CFR 2.201 unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/NRC/ADAMS/index.html> (the Public Electronic Reading Room).

Sincerely,

/RA/

Carl J. Paperiello
Deputy Executive Director
Materials, Research and State Programs

Docket No. 030-00001
License No. 24-04206-01

Enclosures:

1. Notice of Violation and Proposed
Imposition of Civil Penalty
2. NUREG/BR-0254 Payment Methods (Licensee only)

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State of Missouri

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Mallinckrodt, Inc.
St. Louis, Missouri

Docket No. 030-00001
License No. 24-04206-01
EA-00-178

During an NRC inspection conducted July 17 through 19, and August 3 through 4, 2000, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, May 1, 2000, the NRC proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

A. Violations Assessed a Civil Penalty

1. 10 CFR 20.1201(a)(2)(ii) requires, with exceptions not applicable here, that the licensee control the occupational dose to the skin or to any extremity of individual adults to an annual dose limit of 50 rem shallow-dose equivalent.

10 CFR 20.1003 defines occupational dose, in part, as the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation.

Contrary to the above, between 1996 and 2000, the licensee did not limit the annual occupational dose to the extremity of fifteen adults to 50 rem shallow-dose equivalent. Specifically,

- a. one individual working on the dry-top-eluting generator manufacturing line received at least 510 rem shallow-dose equivalent to the thumb and index finger of the right hand on March 31, 2000.
- b. ten individuals assigned primarily to the indium-111 processing line received in excess of 50 rem to the finger tips of their left hands between 1996 and 2000, as follows:
 - i. Individual A received total doses to the finger tips of 193, 124, and 103 rem shallow-dose equivalent in calendar years 1997 through 1999, respectively.
 - ii. Individual B received total doses to the finger tips of 91, 62, 319, and 307 rem shallow-dose equivalent in calendar years 1996 through 1999, respectively.
 - iii. Individual C received total doses to the finger tips of 293, 315, and 114 rem shallow-dose equivalent in calendar years 1997 through 1999, respectively.
 - iv. Individual D received total doses to the finger tips of 171 and 299 rem shallow-dose equivalent in calendar years 1997 and 1998, respectively.
 - v. Individual E received total doses to the finger tips of 56 and 59 rem shallow-dose equivalent in calendar years 1996 and 1997, respectively.
 - vi. Individual F received a total dose to the finger tips of 132 rem shallow-dose equivalent in calendar year 1996.

- vii. Individual G received total doses to the finger tips of 60 and 80 rem shallow-dose equivalent in calendar years 1997 and 1998, respectively.
 - viii. Individual H received total doses to the finger tips of 118 and 71 rem shallow-dose equivalent in calendar years 1999 and 2000, respectively.
 - ix. Individual I received total doses to the finger tips of 130 and 58 rem shallow-dose equivalent in calendar years 1996 and 1997, respectively.
 - x. Individual J received a total dose to the finger tips of 54 rem shallow-dose equivalent in calendar year 2000.
- c. four individuals assigned primarily to the Sterility Laboratory received in excess of 50 rem to the finger tips of their hands between 1997 and 1999, as follows:
- i. Individual K received total doses to the finger tips of 81, 90, and 68 rem shallow-dose equivalent in calendar years 1997 through 1999, respectively.
 - ii. Individual L received total doses to the finger tips of 81, 96, and 81 rem shallow-dose equivalent in calendar years 1997 through 1999, respectively.
 - iii. Individual M received a total dose to the finger tips of 76 rem shallow-dose equivalent in calendar year 1998.
 - iv. Individual N received a total dose to the finger tips of 93 rem shallow-dose equivalent in calendar year 1997. (01011)
2. 10 CFR 20.1501 requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the magnitude and extent of radiation levels, and concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present.
- Pursuant to 10 CFR 20.1003, *survey* means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation.
- 10 CFR 20.1201(c) requires, in part, that the assigned shallow-dose equivalent must be for the part of the body receiving the highest exposure. The shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure.
- Contrary to the above, between 1996 and 2000, the licensee did not make surveys to assure that the assigned shallow-dose equivalent was for the part of the body receiving the highest exposure. Specifically, the licensee assigned shallow-dose equivalents to the finger tips of occupationally exposed adults based on the results of ring badge dosimeters that were not in the region of highest potential exposure, and the licensee did not use other radiation measurements to determine compliance with the occupational dose limits. (01021)
3. 10 CFR 20.1101(b) requires that the licensee use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve

occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

Contrary to the above, between January 1, 1997, and April 28, 2000, the licensee did not use procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses in its Sterility Laboratory and its radioactive material packaging line that were ALARA. Specifically,

- a. the licensee did not use vial and syringe shields (engineering controls) when handling millicurie quantities of phosphorus-32, technetium-99m, and iodine-131, and the resultant extremity doses were not ALARA.
- b. the licensee did not use procedures and engineering controls based upon sound radiation protection principles during the labeling of vials containing millicurie quantities of indium-111, and the resultant total extremity doses were not ALARA. (01031)

This is a Severity Level I problem (Supplement IV).
Civil Penalty - \$125,000

B. Violations Not Assessed a Civil Penalty

1. 10 CFR 20.1501 requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the magnitude and extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present.

Pursuant to 10 CFR 20.1003, *survey* means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation.

10 CFR 20.1201(a)(2)(ii) requires, with exceptions not applicable here, that the licensee control the occupational dose to the skin or to any extremity of individual adults to an annual dose limit of 50 rem shallow-dose equivalent.

Contrary to the above, the licensee did not make surveys that were necessary for the licensee to comply with the regulations in 10 CFR Part 20 and were reasonable under the circumstances to evaluate the extent of radiation levels. Specifically, on July 31, 2000, the licensee performed surveys that were inadequate to evaluate the potential hazards associated with the removal of a generator column containing 703 gigabecquerels (19 curies) of molybdenum-99, exhibiting surface radiation levels as high as 0.5 sievert (50 rem) per second, from a generator shield and the column was removed by hand. This survey was necessary for the licensee to assure compliance with 10 CFR 20.1201(a)(2)(ii). (02013)

This is a Severity Level III violation (Supplement IV).

2. Condition 20.A. of License No. 24-04206-01 requires that the licensee conduct its program in accordance with statements, representations, and procedures contained in a December 26, 1991 application, and other referenced documents.

Section 3.4, "Safety Evaluations," of the licensee's Radiation Protection Program, submitted as an attachment to the referenced application, and last revised by the Radiation Safety Committee on December 20, 1993, states that the Radiation Safety Committee must perform a radiological evaluation of new proposed uses of radioactive material and approve them prior to use.

Contrary to the above, as of July 19, 2000, the Radiation Safety Committee did not perform a radiological evaluation of the dry-top-eluting generator manufacturing line and approve it prior to its first use in, or about, February 1995. (02024)

This is a Severity Level IV violation (Supplement VI).

The NRC has concluded that: the reasons for the violations are already adequately addressed in Inspection Report No. 030-00001/2000-003(DNMS); information regarding initial corrective actions is documented in your letter dated May 26, 2000; and, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance is achieved will be submitted in the schedule of corrective actions required by the June 22, 2000, Confirmatory Order Modifying License. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator, Region III, 801 Warrenville, Road, Lisle, 60532, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

The Licensee may pay the civil penalty proposed above in accordance with NUREG/BR-0254 and by submitting to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, a statement indicating when and by what method payment was made, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty, in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.C.2 of the Enforcement Policy should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is

directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due that subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234(c) of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, statement as to payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: R. W. Borchardt, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to J. E. Dyer, Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, 60532.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/NRC/ADAMS/index.html> (the Public Electronic Reading Room). Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 21st day of December, 2000